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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
FORD, ALLISON M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/940,682

Applicant(s)

TOWNSEND, DAVID E.

Examiner

ALLISON M. FORD

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 7, 10-13, 15, 16, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 10-13, 15, 16, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants response of 5 December 2007 have been received and entered into the application file. Claims 1 and 25 have been amended; claims 2-4, 6, 8, 9, 14 and 17-24 are cancelled; claims 1, 5, 7, 10-13, 15, 16, 25 and 26 remain pending in the current application, all of which have been considered on the merits. All arguments have been fully considered, and are each addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn/overcome.

Priority

Acknowledgement is made of applicant's claim for priority to provisional application 60/228,956, filed 28 August 2000, priority under 119(e). This provisional application provides support for all claims; thus all claims are given the effective filing date of 28 August 2000.

Applicant's claim for the benefit as a CIP of prior-filed application US 08/484,593 (now US Patent 6,387,650) under 35 U.S.C. 120 is also acknowledged. However, this prior filed application does not provide support for the subject matter of current claim 7, which requires the conditionally detectable marker to comprise tetrazolium red. Therefore, only claims 1, 5, 10-16, 25 and 26 receive the benefit of the effective filing date of 7 June 1995; the effective filing date of claim 7, for purposes of applying prior art is considered to be the filing date of the provisional application 60/228,956: 28 August 2000.

Claim Objections

Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in

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independent form. Claim 25 has been amended to incorporate the limitation of claim 26, thus claim 26 no longer limits parent claim 25.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

With regards to the rejection of claims 1, 5, 7, 13, 15, 16 and 25 under 35 USC 112, first paragraph, as lacking written description, Applicants have argued that one of ordinary skill in the art would immediately understand that the inventor was in possession of the claimed species of aminopeptidase substrates at the time the application was filed. Applicants have argued that aminopeptidases were known, and due to their chemical nature and properties, and thus substrates for each aminopeptidase were known.

In response, it is noted that Applicants have disclosed a representative number of aminopeptidases, and suitable substrates would be known in the art, it is also understood that aminopeptidases absent from the target microorganism are not structurally distinct from those known in the art. However, the rejection is not based on a lack of description of aminopeptidases *in general*, but rather the rejection is based on the fact Applicants have not identified which aminopeptidases are specifically *absent* from the target microorganisms, but are *present* in all non-target microorganisms. Without identifying which aminopeptidases fall within this category one could not determine the corresponding substrates which would be appropriate for inclusion in the claimed composition, and thus the invention, as claimed, is not fully described by the specification.

In the language of the analogy provided by Applicants, it is not the specificity or the M&M structure/color that is questioned, but rather it is not known which person is missing from the room (and

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their hair color), thus one cannot determine which color M&M would be left 'in the bag'. Therefore, without identification of the aminopeptidases which are absent from the specific target microorganisms, description of the claimed composition, which must contain an aminopeptidase substrate specific to the missing aminopeptidase, is insufficient and the rejection of record stands:

Claims 1, 5, 7, 13, 15 and 16 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are found to lack written description, as the specification does not disclose which aminopeptidase substrates are encompassed by the claimed composition (being aminopeptidases that are absent from the disclosed target microorganism).

To satisfy the written description requirement, the specification must provide sufficient description of the claimed product (in the instant case, the composition comprising the aminopeptidase substrate, as defined by the claims) to show that Applicant was in possession of the claimed invention.

It is noted the specification does provide numerous aminopeptidase substrates and even numerous L-alanine aminopeptidases, the disclosed species are representative of aminopeptidase substrates, in general, and of L-alanine aminopeptidase substrates; however, the claimed composition does not include "aminopeptidase substrates," in general, or even "L-alanine aminopeptidase substrates," but aminopeptidase substrates *wherein the aminopeptidase is substantially absent from at least one of the listed target microbes*. Therefore, the invention as claimed is directed to a narrower subgenus of aminopeptidase substrates than disclosed in the specification. Even though Applicants have described a *broad* genus than that which they are claiming, the problem of a lack of written description is still present because Applicant's disclosure fails to define or describe a representative number of species which would show Applicant was in possession of the *narrower* subgenus of substrates being claimed.

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When the scope of the claims is narrower than what is disclosed in the specification, there must be support and description for that specific subgenus, by itself, not just as falling within the broader genus. It has been held that disclosure of a “laundry list” of species does not constitute a written description of every species in the genus, much less a subgenus, because it would not “reasonably lead” those skilled in the art to any particular species, See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

It must be shown that Applicant had possession of the invention *as claimed* (i.e. the narrowed subgenus of aminopeptidase substrates which satisfy the claim limitations), and must describe it in a way that would permit one of ordinary skill in the art to immediately envisage the claimed invention (e.g. the narrowed subgenus). Because Applicant has not disclosed specific aminopeptidases that are absent from *each* of the claimed target microbes, one could not immediately envisage which aminopeptidase substrates would appropriately be included in the claimed composition.

With regards to the rejection of claims 1, 5, 7, 10-13, 15 and 16 under 35 USC 112, first paragraph, as lacking enablement, Applicants have argued that the instant specification does provide sufficient guidance and teachings on how to successfully make and use the instant invention to detect all named target microorganisms from mixed samples. Applicants argue that testing various bacteria to determine the presence or absence of aminopeptidase activity is routine, citing Peterson et al, Kampf et al, and Westley et al, and thus such would not constitute undue experimentation. Applicants further argue that the instant composition requires selective growth medium, which is selective for the target microorganisms, and that such selective media was known in the art.

In response to Applicants' argument that testing microorganisms for aminopeptidase activity was routine, it is accepted that means for testing bacteria for aminopeptidase activity was known in the art;

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however, to properly enable an invention, the specification must disclose how to make and use the invention *without undue experimentation* (See Wands, 8 USPQ2d 1404). As the claims currently read, successfully using the composition for the intended use would require determination of an aminopeptidase that is absent in the target microorganisms, yet present in all other non-target microorganisms. While it was known how to carry out the required screening assays, actually performing such assays on *all* microbes is considered to be beyond the boundaries of routine experimentation.

In response to Applicants' argument that selective growth media which would support only the growth of the target microorganism was known in the art, it is respectfully submitted that Applicants are relying on elements not in the presently examined claims. Claim 1 still only requires "a growth-supporting medium for the target microorganism", it does not require the growth-supporting medium to be *specific for* the target microorganism (support growth of target microorganism, suppress growth of non-target microorganisms). As such, the rationale Applicants used in response to the 103 rejection, is applicable to the current claims- Applicants have not claimed a composition that is capable of differentiating between Gram-positive bacteria and *Campylobacter*, as both would provide the same detectable signals. Therefore, the rejection of record stands:

Claims 1, 5, 7, 10-13, 15 and 16 stand rejected under 35 U.S.C. 112, first paragraph, as being enabled for only a limited scope of the instantly claimed invention. The specification, while being enabling for production and use of compositions for identifying a pure culture sample of Gram-negative bacteria as *Campylobacter*, said compositions comprising (i) a conditionally detectable marker that functions as a viability marker; (ii) an L-alanine aminopeptidase substrate; and (iii) a growth-supporting medium for *Campylobacter*, does not reasonably provide enablement for production and use of compositions for detecting any target microorganism in any sample, or even for detecting *Campylobacter* in a mixed sample, or for differentiating between *Campylobacter* and any Gram-positive bacteria, wherein said composition comprises (i) a conditionally detectable marker that functions as a

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viability marker; (ii) a substrate for an aminopeptidase, wherein said aminopeptidase is substantially absent from the target microorganism; and (iii) a growth-supporting medium for *Campylobacter*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue or unreasonable experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). The key word is 'undue,' not experimentation.' " (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicant's claims are directed to a composition for detecting a target microorganism, wherein the composition comprises (i) a conditionally detectable marker that undergoes a color change when reacted upon by a viable microorganism (a 'presumptive indicator'); (ii) an aminopeptidase substrate comprising a signal moiety capable of providing a detectable signal when cleaved, wherein the aminopeptidase which would react upon the substrate is substantially absent from the target microorganism, but is present in non-target microorganisms (a 'confirmation indicator') (See Spec. pg. 17); and (iii) a growth-supporting medium for *Campylobacter*. A target microorganism is detected when a sample, placed in contact with the claimed composition, produces a positive signal by the 'presumptive indicator,' but fails to produce a positive signal by the 'confirmation indicator'; if non-target microorganisms are present, two positive signals would be produced. Though the claims are not directed to a method of using the claimed composition, it is necessary to set forth how the claimed composition would be used, so as to determine whether the disclosure enables one of ordinary skill in the art to successfully make and use the claimed composition.

Therefore, in order to successfully make and use the claimed composition, one of ordinary skill in the art would have to be able to determine (a) a conditionally detectable marker that would undergo a color change when reacted upon by any viable microorganism; and (b) an aminopeptidase substrate comprising a signal moiety that would produce a detectable signal when cleaved by the appropriate aminopeptidase, wherein the aminopeptidase is substantially absent from the target microorganism, but would be present in all non-target microorganisms. A review of the specification shows that sufficient number of viability markers were disclosed in the specification (e.g. Vital Dyes, specifically tetrazolium red), or were otherwise known in the art, to enable the artisan of ordinary skill to be able to select an appropriate viability marker for use in the composition. However, with regards to the aminopeptidase substrate which would satisfy the claim limitations, the specification fails to disclose a representative number of aminopeptidase substrate species which would be suitable for use in the claimed invention, for each of the claimed target microorganisms.

As discussed above, though Applicant has disclosed numerous aminopeptidase substrates, they have not identified which substrates, from the lengthy lists provided, would be suitable for use in the claimed composition for detection of each of the claimed target microorganisms. Within claim 1, the target microorganism are defined as one of *Salmonella*, *Listeria*, *E. coli* OH157, *Campylobacter*, and *Staphylococcus aureus*; claim 25 is limited to *Campylobacter*. The specification only discloses that *Campylobacter* lacks L-alanine aminopeptidase (See Spec, page 18); there are no teachings or discussion of additional aminopeptidases which are substantially absent from *Campylobacter*, or of any aminopeptidases which are substantially absent from each of *Salmonella*, *Listeria*, *E. coli* OH157, or *Staphylococcus aureus*. Therefore, beyond the use of L-alanine aminopeptidase substrates for detection of *Campylobacter*, in order to successfully make and use the claimed composition, one of ordinary skill in the art would first have to conduct experimentation to determine which, if any, aminopeptidases are substantially absent from each of the claimed target microorganisms and which is present in all non-

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target microorganisms; such is considered to amount to undue experimentation. While it would not be outside the purview of the artisan of ordinary skill to test various microorganisms for different aminopeptidases, due to the large number of aminopeptidases known (which would each need to be tested), and the almost infinite number of microorganisms (again, which would each need to be tested in order to ensure the target microorganism is the only one that substantially lacks the aminopeptidase in question), the amount of experimentation which would be required on the part of the artisan would be considerably extensive and undue. The disclosure does not even present a narrowed range of probable or likely aminopeptidases which could be reasonably expected to be present in all but the target microorganism.

The only embodiment Applicant has clearly enabled is for when the composition is intended for identification of a pure culture sample as *Campylobacter*, wherein the composition comprises (i) a conditionally detectable marker that functions as a viability marker (e.g. tetrazolium red); (ii) an L-alanine aminopeptidase substrate; and (iii) a growth substrate for *Campylobacter*. However, even though Applicant has disclosed how to make this particular composition, it is noted that such a composition would only be able to successfully identify a pure culture sample as *Campylobacter* if it was known previously that the culture was Gram-negative. It was known most Gram-negative bacteria contain the L-alanine aminopeptidase in their cell wall; *Campylobacter* spp are the only Gram-negative bacteria that are negative for L-alanine aminopeptidase. All Gram-positive bacteria are negative for L-alanine aminopeptidase (See, e.g. Manafi et al). Therefore, the composition in question would only be able to identify a L-alanine aminopeptidase negative sample if the sample was free of L-alanine aminopeptidase positive microorganisms; the presence of any L-alanine aminopeptidase containing bacteria in the sample will prevent the identification (detection) of *Campylobacter*. Both *Campylobacter* and all Gram-positive bacteria samples will give the same reading (positive 'presumptive indicator'/negative 'confirmation

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indicator'); therefore it would be necessary to know the same being applied is not Gram-positive, but Gram-negative.

Beyond this scope, Applicant has not enabled one skilled in the pertinent art to make and use the claimed invention without undue or unreasonable experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant claims 1 and 25 are directed to a composition for detecting a target microorganism, specifically *Campylobacter*, in a sample, the composition comprising (i) a conditionally detectable marker that undergoes a color change when reacted upon by a viable microorganism; (ii) a substrate for an aminopeptidase, wherein said substrate comprises a signal moiety that provides a detectable signal when cleaved; and (iii) a growth supporting medium for the target microorganism; and wherein the (i) conditionally detectable marker and (ii) the substrate for an aminopeptidase are not the same molecule. Claim 7 requires the conditionally detectable marker to be tetrazolium red. Claims 10 and 26 require the aminopeptidase to be L-alanine aminopeptidase. Claims 11 and 12 require the substrate to be selected from the disclosed group, specifically L-alanin-7-amido-4-methylcoumarin.

With regards to the rejection of claims 1, 5, 7, 10-13, 15, 16, 25 and 26 under 35 USC 103(a), Applicants argue that the combination of cited references fails to support a *prima facie* case of obviousness. Specifically, Applicants argue that one of ordinary skill in the art would not have been motivated to add a viability marker (Tuompo et al) to the composition of Manafi et al, as such a viability

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marker would be unnecessary because formation of colonies is already indicative of viability. Furthermore, Applicants argue that the cited references fail to disclose use of a growth medium which is selective for the target microorganism, thus, even if combined, the products of the prior art would not be capable differentiating between *Campylobacter* and Gram-positive bacteria. Applicants submit the product of the prior art would only be capable of detecting non-*Campylobacter*, Gram-negative bacteria, which is a 'non-target' microorganism, and thus the produce isn't suitable for the intended purpose of the instant invention.

In response to Applicants' argument that one of ordinary skill in the art would not have been motivated to add a viability marker (tetrazolium red) based on the fact that all viable microbes would form colonies (and thus be identifiable as colony forming units) it is respectfully submitted that providing additional confirmation means (confirmation of viability) would have been appropriate to reduce objectivity in reading the results and/or in situations wherein the results are read automatically (such as by machine). Colored detection markers would also have desirable for teaching purposes, to make the results clearer and/or easier to read. While tetrazolium red or other vitality markers may be redundant, their inclusion is still obvious and does not make the instant claims patentable. It is further noted the conditionally detectable marker of the instant invention functions in the same redundant manner- to confirm the presence of target microorganisms, wherein their presence could alternatively be confirmed by identification of colony forming units. Generally, inclusion of additional confirmation markers, while their function may be redundant, is still obvious and does not add a point of novelty.

In response to Applicants' argument that the combination of cited references fails to suggest use of a *selective* growth media, selective for development of target microorganism, it is respectfully submitted that Applicants are relying on limitations not in the presently examined claims. Claim 1 only requires a "growth-supporting medium for the target microorganism", it does not specify any selective action towards the target microorganism or against non-target microorganisms. Claim 25, as amended

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now requires the growth-supporting medium to be for the 'specific enrichment of *Campylobacter*', however, while more specific, in giving the term its broadest reasonable interpretation, this term still does not specify that the growth medium inhibits non-*Campylobacter* species, but only requires that growth of *Campylobacter* be enriched. Thus the claims fail to recite the limitation being relied upon. For these reasons the rejection of record stands:

Claims 1, 5, 7, 10-13, 15, 16, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Manafi et al (J Appl Bacteriol, 1990) in view of Molina et al (Enfermedades Infecciosas y Microbiologia Clinica, 1991) and Tuompo et al (US Patent 5,420,017).

Manafi et al disclose a method and composition for detecting the presence of Gram-negative bacteria in a sample. The composition of Manafi et al comprises the conditionally detectable marker L-alanine-7-amido-4-methylcoumarin (AAMC), which produces a fluorescent color change when cleaved by the L-alanine-aminopeptidase found in the cell wall of substantially all Gram-negative bacteria except for *Campylobacter* (See Manafi et al, See pages 823, first paragraph & Molina et al, abstract). Manafi et al disclose the fluorogenic substrates were incorporated into Plate Count Agars (which necessarily contain the necessary nutrients and growth factors necessary for the survival of the plated microorganisms, as the bacterial cultures successfully grew on the agars) (See Manafi et al, Pg. 823, col. 2, "Media and Chemicals"). The method of Manafi et al is capable of differentiating between Gram-negative and Gram-positive bacteria as a positive result (fluorescent indicator) is only achieved when Gram-negative bacteria having the L-alanine aminopeptidase are present in the sample.

Tuompo et al also disclose a method and kit for detecting microorganisms in a sample. The method relies on use of a composition comprising a chromogenic reagent in an amount effective to detect bacteria; preferably the chromogenic reagent is a tetrazolium salt, particularly triphenyltetrazolium chloride (tetrazolium red), which produces a color change from colorless to red upon biochemical reduction by viable bacteria (See Tuompo et al, col. 2, ln 25-35 & claim 4).

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It would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the composition of Manafi et al, which comprised AAMC in an agar plate, to further include tetrazolium red, as taught by Tuompo et al. Including the viability marker tetrazolium red in the agar plate of Manafi et al, would provide an extra measure of quality control in the methods of Manafi et al, as the viability marker would provide a positive reading, indicating the bacteria were successfully transferred in a viable state to the agar plates. As disclosed, the composition of Manafi et al only provides a detectable signal if the sample contains L-alanine aminopeptidase, if the sample is L-alanine aminopeptidase negative, no signal is produced, yet there is no way to determine if the sample is merely negative for L-alanine aminopeptidase or if the sample was not successfully plated. Including the viability marker tetrazolium red would provide an extra measure to ensure the sample was transferred successfully and that a false negative was not obtained due to a dead sample.

Therefore, the invention as a whole would have been prima facie case obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651